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## Amendments to the Claims:

- 12. (Currently Amended) A method of treating a subject for a cancer characterized by overexpression of the HER2 receptor protein-in a subject, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and interleukin-2 (IL-2) or biologically active variant thereof, wherein said concurrent therapy comprises administering to said subject at least one therapeutically effective dose of said IL-2 or variant thereof in combination with a dosing regimen for said anti-HER2 antibody or fragment thereof, wherein said dosing regimen for said anti-HER2 antibody or fragment thereof, wherein said subject at least one therapeutically effective dose of said anti-HER2 antibody or fragment thereof, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 1.0.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.5 mfU/m² MIU/m² to about 4.0 mfU/m² MIU/m²; wherein said variant of said IL-2 has at least 70% sequence identity with said IL-2 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4, and wherein said fragment of said anti-HER2 antibody retains the ability of said anti-HER2 antibody to bind the HER2 receptor protein.
- 13. (Currently Amended) The method of claim 12, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 mlU/m<sup>2</sup> MIU/m<sup>2</sup> to about 3.0 mlU/m<sup>2</sup> MIU/m<sup>2</sup>.
- 14. (Currently Amended) The method of claim 13, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 mfU/m<sup>2</sup> MfU/m<sup>2</sup> to about 1.5 mfU/m<sup>2</sup> MfU/m<sup>2</sup>.

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- 15. (Currently Amended) The method of claim 14, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is about 4.0 mg/m<sup>3</sup>4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 mlU/m<sup>3</sup> MIU/m<sup>2</sup>.
- (Currently Amended) A method of treating a subject for a cancer characterized 16. by overexpression of the HER2 receptor protein in a subject, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and interleukin-2 (IL-2) or biologically active variant thereof, wherein said concurrent therapy comprises a first administration of a therapeutically effective dose of said IL-2 or variant thereof on day 1 of a treatment period followed by a first administration of a therapeutically effective dose of said anti-HER2 antibody or fragment thereof within 6 days of said first administration of said therapeutically effective dose of said IL-2 or variant thereof to said subject, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.5 mHU/m<sup>2</sup> MIU/m<sup>2</sup> to about 4.0 mHJ/m<sup>2</sup> MIU/m<sup>2</sup>; wherein said variant of said 11-2 has at least 70% sequence identity with said IL-2 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4. and wherein said fragment of said anti-HER2 antibody retains the ability of said anti-HER2 antibody to bind the HER2 receptor protein.
- by overexpression of the HER2 receptor protein-in-a-subject, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and interleukin-2 (IL-2) or biologically active variant thereof, wherein said concurrent therapy comprises multiple dosing of a therapeutically effective dose of said anti-HER2 antibody or fragment thereof and a therapeutically effective dose of said IL-2 or variant thereof, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant

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thereof is in the range from about 0.5 mIU/m<sup>2</sup> MIU/m<sup>2</sup> to about 4.0 mIU/m<sup>2</sup> MIU/m<sup>2</sup>; wherein said variant of said IL-2 has at least 70% sequence identity with said IL-2 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4, and wherein said fragment of said anti-HER2 antibody retains the ability of said anti-HER2 antibody to bind the HER2 receptor protein.

- 18. (Currently Amended) The method of claim 17, wherein said multiple dosing comprises administering to said subject said therapeutically effective dose of said IL-2 or variant thereof and said therapeutically effective dose of said anti-HER2 antibody or fragment thereof during an introductory cycle, wherein said introductory cycle comprises daily administration of said therapeutically effective dose of said IL-2 or variant thereof on day 1 of said introductory cycle through day 20 of said introductory cycle, and a single administration of said therapeutically effective dose of said anti-HER2 untibody or fragment thereof on day 7 of said introductory cycle.
- 19. (Currently Amended) The method of claim 18, further comprising administering said therapeutically effective dose of said IL-2 or variant thereof and said therapeutically effective dose of said anti-HER2 antibody or fragment thereof during at least one subsequent cycle, wherein said subsequent cycle comprises daily administration of said therapeutically effective dose of said IL-2 or variant thereof on day 1 of said subsequent cycle through day 14 of said subsequent cycle, and administration of said therapeutically effective dose of said anti-HER2 antibody or fragment thereof on day 1 of said subsequent cycle.
- 20. (Currently Amended) The method of claim 18, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of <u>said IL-2</u> or variant thereof an intermediate dose of a pharmaceutical composition comprising said IL-2 or variant thereof, wherein said intermediate dose comprises <u>is about 12.0 mIU/m<sup>2</sup> MIU/m<sup>2</sup> IL-2-or-variant-thereof</u>.

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- 21. (Currently Amended) The method of claim 19, further comprising intermediate-dose IL-2 pulsing on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of a pharmaceutical composition comprisingsaid IL-2 or variant thereof, wherein said intermediate dose comprises is about 12.0 mlU/m² MIU/m² IL-2 or variant thereof.
- 22. (Previously presented) The method of claim 12, wherein said IL-2 or variant thereof is administered subcutaneously.
- 23. (Previously presented) The method of claim 12, wherein said anti-HER2 antibody comprises at least one human constant region.
- 24. (Currently amended) The method of claim 12, wherein said anti-HER2 antibody is selected from the group consisting of 4D5 and 520C9, or fragment thereofa humanized anti-HER2 antibody, a chimeric anti-HER2 antibody, or a human anti-HER2 antibody, and said fragment thereof retains the ability of said humanized, chimeric, or human anti-HER antibody to hind the HER2 receptor protein.
- 25. (Currently Amended) The method of claim 2412, wherein said anti-HER2 antibody is 4D5 or a humanized, chimeric, or human form thereof of a murine antibody selected from the group consisting of 4D5 and 520C9.
- 26. (Currently Amended) The method of claim 12, wherein said therapeutically effective dose of said IL-2 or variant thereof is administered as a pharmaceutical composition selected from the group consisting of a stabilized-monomeric IL-2 pharmaceutical composition, a multimeric pharmaceutical IL-2 composition, a stabilized-lyophilized IL-2 pharmaceutical composition, and a stabilized-spray-dried IL-2 pharmaceutical composition.

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- 27. (Currently Amended) The method of claim 26, wherein said IL-2 or variant thereof is recombinantly produced IL-2 having an amino acid sequence-for-human IL-2 or variant thereof and said IL-2 is human IL-2.
- 28. (Currently amended) The method of claim 27, wherein said variant thereof has an amino acid sequence having at least about 70% sequence identity to the amino acid sequence for said human IL-2 is des-alanyl-1, serine-125 human interleukin-2.
- 29. (Currently Amended) The method of claim 28, wherein said anti-HER2 antibody or fragment thereof comprises at least one human constant region.
- 30. (Currently Amended) The method of claim 28, wherein said anti-HER2 antibody is selected from the group consisting of 4D5 and 520C9, or fragment thereof a humanized anti-HER2 antibody, a chimeric anti-HER2 antibody, or a human anti-HER2 antibody, and said fragment thereof retains the ability of said humanized, chimeric, or human anti-HER antibody to bind the HER2 receptor protein.
- 31. (Currently Amended) The method of claim 3028, wherein said anti-HER2 antibody is 4D5 or a humanized, chimeric, or human form thereofof a murine antibody selected from the group consisting of 4D5 and 520C9.
- 32. (Currently Amended) The method of claim 16, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 mlU/m<sup>2</sup> MIU/m<sup>2</sup> to about 3.0 mlU/m<sup>2</sup> MIU/m<sup>2</sup>.
- 33. (Currently Amended) The method of claim 32, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 3.0

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mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8  $\frac{mHU/m^2}{m^2}$  to about 1.5  $\frac{mHU/m^2}{m^2}$ .

- 34. (Currently Amended) The method of claim 33, wherein said therapeutically effective dose of <u>said</u> anti-HER2 antibody or fragment thereof is about 4.0 mg/m<sup>2</sup> 4.0 mg/kg and wherein said therapeutically effective dose of <u>said IL-2</u> or variant thereof is about 1.0 mIU/m<sup>2</sup> MIU/m<sup>2</sup>.
- 35. (Currently Amended) The method of claim 17, wherein said therapeutically effective dose of <u>said</u> anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of <u>said IL-2</u> or variant thereof is in the range from about 0.6 mIU/m<sup>2</sup> MIU/m<sup>2</sup> to about 3.0 mIU/m<sup>2</sup> MIU/m<sup>2</sup>.
- 36. (Currently Amended) The method of claim 35, wherein said therapeutically effective dose of <u>said</u> anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of <u>said IL-2</u> or variant thereof is in the range from about 0.8 mIU/m<sup>2</sup> MIU/m<sup>2</sup> to about 1.5 mIU/m<sup>2</sup> MIU/m<sup>2</sup>.
- 37. (Currently Amended) The method of claim 36, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is about 4.0 mg/m<sup>2</sup> and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 mHU/m<sup>2</sup> MTU/m<sup>2</sup>.
- 38. (Currently Amended) The method of claim 18, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 mIU/m<sup>2</sup> MIU/m<sup>2</sup> to about 3.0 mIU/m<sup>2</sup> MIU/m<sup>2</sup>.
- 39. (Currently Amended) The method of claim 38, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 3.0 RTA01/2[56933v]

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mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 mTU/m<sup>2</sup> MIU/m<sup>2</sup> to about 1.5 mTU/m<sup>2</sup> MIU/m<sup>2</sup>.

- (Currently Amended) The method of claim 39, wherein said therapeutically 40. effective dose of said anti-HER2 antibody or fragment thereof is about 4.0 mg/m<sup>2</sup> 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 mHJ/m<sup>2</sup>  $MIU/m^2$
- 41. (Currently Amended) The method of claim 19, further comprising intermediatedose IL-2 pulsing on days 8-10 of said introductory cycle and on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of a pharmaceutical composition eemprising said IL-2 or variant thereof, wherein said intermediate dose eemprises is about 12.0 mIU/m<sup>2</sup>-IL-2 or variant thereof.
- 42. (Currently Amended) A method of treating a subject for a cancer characterized by overexpression of the HER2 receptor protein-in-a-subject, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and interleukin-2 (IL-2) or biologically active variant thereof, wherein said concurrent therapy comprises daily administration of a therapeutically effective dose of said IL-2 or variant thereof on day 1 of an introductory cycle through day 20 of said introductory cycle, and a single administration of a therapeutically effective dose of said anti-HER2 antibody or fragment thereof on day 7 of said introductory cycle; wherein said variant of said IL-2 has at least 70% sequence identity with said IL-2 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4, and wherein said fragment of said anti-HER2 antibody retains the ability of said anti-HER2 antibody to bind the HER2 receptor protein.
- 43. (Currently Amended) The method of claim 42, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 1.0 RTA01/2156933v1

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mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said 1L-2 or biologically active variant thereof is in the range from about 0.5 mIU/m<sup>2</sup> MIU/m<sup>2</sup> to about 4.0 mIU/m<sup>2</sup> MIU/m<sup>2</sup>.

- 44. (Currently Amended) The method of claim 43, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 mHU/m<sup>2</sup> MTU/m<sup>2</sup> to about 3.0 mHU/m<sup>2</sup> MTU/m<sup>2</sup>.
- 45. (Currently Amended) The method of claim 44, wherein said therapeutically effective dose of <u>said</u> anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of <u>said IL-2</u> or variant thereof is in the range from about 0.8 mHU/m<sup>2</sup> MTU/m<sup>2</sup> to about 1.5 mHJ/m<sup>2</sup> MTU/m<sup>2</sup>.
- 46. (Currently Amended) The method of claim 45, wherein said therapeutically effective dose of <u>said</u> anti-HER2 antibody or fragment thereof is about 4.0 mg/m<sup>2</sup> 4.0 mg/kg and wherein said therapeutically effective dose of <u>said\_IL-2</u> or variant thereof is about 1.0 mlU/m<sup>2</sup> MIU/m<sup>2</sup>.
- 47. (Currently Amended) The method of claim 42, further comprising administering said therapeutically effective dose of said IL-2 or variant thereof and said therapeutically effective dose of said anti-HER2 antibody or fragment thereof during at least one subsequent cycle, wherein said subsequent cycle comprises daily administration of said therapeutically effective dose of said IL-2 or variant thereof on day 1 of said subsequent cycle through day 14 of said subsequent cycle, and administration of said therapeutically effective dose of said anti-HER2 antibody on day 1 of said subsequent cycle.
- 48. (Currently Amended) The method of claim 42, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle, wherein said pulsing comprises

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administering in place of said therapeutically effective dose of <u>said IL-2</u> or variant thereof an intermediate dose of a pharmaceutical composition comprisingsaid IL-2 or variant thereof, wherein said intermediate dose comprises is about 12.0 mIU/m<sup>2</sup> MIU/m<sup>2</sup> IL-2 or variant thereof.

- 49. (Currently Amended) The method of claim 47, further comprising intermediate-dose IL-2 pulsing on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of <u>said\_IL-2</u> or variant thereof an intermediate dose of <u>a pharmacontical composition comprising\_said\_IL-2</u> or variant thereof, wherein said intermediate dose comprises about 12.0 mlU/m<sup>2</sup> MIU/m<sup>2</sup> IL-2 or variant thereof.
- 50. (Currently Amended) The method of claim 47, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle and on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of a pharmaceutical composition comprisingsaid IL-2 or variant thereof, wherein said intermediate dose comprises is about 12.0 mIU/m<sup>2</sup> IL-2 or variant thereof.
  - 51. (New) The method of claim 12, wherein said cancer is breast cancer.
- 52. (New) The method of claim 51, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 and 520C9.
- 53. (New) The method of claim 52, wherein said IL-2 or variant thereof is recombinantly produced, and wherein said IL-2 is human IL-2.
  - 54. (New) The method of claim 16, wherein said cancer is breast cancer.
- 55. (New) The method of claim 54, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 and 520C9.

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- 56. (New) The method of claim 55, wherein said IL-2 or variant thereof is recombinantly produced, and wherein said IL-2 is human IL-2.
  - 57. (New) The method of claim 17, wherein said cancer is breast cancer.
- 58. (New) The method of claim 57, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 and 520C9.
- 59. (New) The method of claim 58, wherein said IL-2 or variant thereof is recombinantly produced, and wherein said IL-2 is human IL-2.
  - 60. (New) The method of claim 42, wherein said cancer is breast cancer.
- 61. (New) The method of claim 60, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 and 520C9.
- 62. (New) The method of claim 61, wherein said IL-2 or variant thereof is recombinantly produced, and wherein said IL-2 is human IL-2.